

REMARKS

This amendment is in response to the Official Action dated April 27, 2009. Claims 1, 4, 6, 10, 11 and 13 have been amended. The support for the amendment can be found at paragraphs [0080], [0081] and [0116] – [0119] of US-2006/0247546-A1, which is a publication of this application. Claims 14 and 15 have been added. No claims have been canceled. Claims 1-15 are now pending in this application. Claims 1, 4, 6, 10, 11, 13 and 14 are independent claims. No new matter has been added. Reconsideration and allowance is requested in view of the following remarks.

35 USC § 103 Rejections

Claims 1-4 and 6-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Turcott (US 6,409,675, hereinafter referred to as “Turcott ‘675) in view of Montserrat et al (hereinafter referred to as “Montserrat”) further in view of Krachman et al (hereinafter referred to as “Krachman”). Applicant respectfully traverses this rejection.

Claim 1 recites:

An examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure, the apparatus comprising:

a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient;

an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form;

an editor part for selecting a zone to be subjected to data processing among biological information including the airflow information and the electrocardiogram wave form of the subject patient through visual identification; and

an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.

Turcott '675 fails to disclose, suggest or teach "***a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient.***"

However, Turcott '675 arguably discloses an apparatus for monitoring the hemodynamic status of a patient. Specifically, Turcott '675 arguably discloses an implantable monitor; in contrast the monitor in the current invention is attached on the body of a patient. Data can then be conveyed routinely and automatically, allowing more computationally demanding analysis to be done by an external device.

Indeed, Turcott '675 arguably discloses an implantable monitor, in contrast to a non-implantable biological information monitoring system. Turcott '675 states that "in another embodiment the monitor is not implanted but rather is attached or worn externally by the patient daily for extended periods, such as during sleep." (Column 7, lines 25-27) However, the non-implanted monitor in Turcott '675 has ONLY the vascular plethysmography and arterial O₂ saturation sensors as recited below (Column 11, lines 41-44).

As with most of the sensors described here, the vascular plethysmography and arterial O₂ saturation sensors can be used in noninvasive, external embodiments, in contrast to incorporation in an implantable monitor.

In contrast, the current invention claims “*a non-implantable biological information monitoring system*” which is not disclosed or suggested by Turcott ‘675.

The Office Action, nevertheless, on page 3 and 7 of the Office Action, has argued that Turcott ‘675 is not stating that it is only the two sensors that can be placed in a non-implantable device. The Office action goes on to argue that Turcott ‘675 is suggesting that these two sensors, along with most of the other sensors described, can be used in an external embodiment, while they cannot be used as an implantable monitor. This is wholly inaccurate.

Turcott ‘675 specifically states “despite the cost advantages of an external embodiment, such an approach necessarily requires patient cooperation. Because of the disadvantages associated with this, as described above in Discussion of the Prior Art, the preferred embodiment for these sensors is in an implanted, extravascular configuration.”

In any case, the reading by the Office Action is mere hindsight. Col. 7, lines 25-27 merely invites a scientist to “explore new technology that seems a promising field of experimentation. The [Turcott ‘675] statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion...does not make the invention obvious.” *Ex parte Obukowicz*, 27 USPQ2d 1063 (B.P.A.I. 1992).

In addition, the Office Action indicates Turcott ‘675 “does not directly teach an electrode for measuring ECGs that are stuck on the skin of the subject,” but indicates that this feature is disclosed in prior art of Turcott ‘675. This is inaccurate.

The two generally worn external recorders are Holter recorders, which record continuously for an extended period of time. However, both of these recorders are designed for short-term use and require active patient participation. As stated in the specification, the

disadvantages of prior art of Turcott '675 are overcome by Applicant's claimed invention (see paragraph [0003], [0008] and 0019)). For instance, performing home oxygen therapy to carry out the oxygen therapy at home enables continuation of oxygen therapy for a long period of time under fewer economical and social burdens and without the need for hospitalization. Further, Turcott '675 explicitly states the recorders are limited to recording the electrical activity of the heart and do not attempt to measure or quantify the hemodynamic status of the patient beyond screening for cardiac arrhythmias.

Moreover, by making the biological information system non-implantable, the biological information monitor may be attached to a patient who is movable with the monitor. A doctor may attach sensors of the recording part to the patient. The patient may go home, and biological data can be captured for 24 hours (see page 39, line 20 through page 40, line 14). Thus no large scale equipments needed for a conventional monitor, such as PSG, can be eliminated, and a doctor or his/her supporting staff may identify effectiveness of oxygen therapy applied to the patient (see page 49, lines 10-17). Thus the present invention makes it easy to check the patient while sleeping at home during his/her daily life.

On the other hand, as for implanted monitor as described in Turcott '675, the patients are limited to those having the monitor implanted. Further, the matters to be monitored are limited. Once the monitor is implanted, a doctor cannot change or adjust the location of the monitor in the cases where biological information such as breathing information or pulse information cannot be properly obtained. This is extremely inconvenient.

Turcott '675 fails to disclose, suggest or teach "***an editor part for selecting a zone to be subjected to data processing among biological information including the airflow information and the electrocardiogram wave form of the subject patient through visual identification***" and "***an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient within the zone selected by the editor part.***"

As stated at paragraphs [0080], [0081] and [0116] – [0119] of US-2006/0247546-A1, which is a publication of this application, for analysis of biological information of a subjected patient, the biological information obtained at a medical institution is sent from a medical institution to a specialized analysis center, where the analysis is conducted by an expert engineer. Upon the analysis, the engineer selects through visual identification a zone that presents a characteristic which is believed to be useful for diagnosis from the data in the entire zone. The analysis results are sent back to the medical institution where a doctor review the results. Thus the doctor does not have to review the entire zone of the information and precious time for the doctor can be saved.

On the other hand, Turcott '675 does not disclose, suggest the editor part that identifies a selected zone of an biological information that is available for review by a doctor. According to the disclosure of Turcott '675, the doctor must review the entire zone of the information.

Further, Turcott '675 does not disclose or even suggest “[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure.” The Office Action acknowledged that Turcott '675 does not disclose or even suggest “[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure,” but alleges that Montserrat further in view of Krachman does. Again, this is inaccurate.

Montserrat further in view of Krachman does not remedy the deficiencies of Turcott '675, as the various features recited above are also absent form Montserrat further in view of Krachman. For example, Applicant's claimed features of “a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient,” is not disclosed by Montserrat further in view of Krachman.

Montserrat discloses Continuous Positive Airway Pressure (CPAP) is effective for sleep apnea/hypopnea syndrome. By the forgoing amendment, the subject matter is different from the disclosure of Montserrat. Furthermore, according to dictionary.com, CPAP is defined as “[a] technique of respiratory therapy for individuals breathing with or without mechanical assistance in which airway pressure is maintained above atmospheric pressure throughout the respiratory cycle by pressurization of the ventilatory circuit (visited www.dictionary.com on April 21, 2008).”

Krachman discloses a comparison of oxygen therapy with nasal continuous positive airway pressure on Cheyne-Stokes Respiration During Sleep in Congestive Heart Failure. In particular, Krachman finds oxygen therapy and nasal CPAP therapy are equally effective in decreasing the AHI and improving nocturnal oxygenation in patients.

Montserrat further in view of Krachman does not mention a non-implantable biological information monitoring system.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 1 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the implantable hemodynamic monitor of Turcott ‘675 with the CPAP treatment of Montserrat with the oxygen therapy and nasal CPAP of Krachman.

Independent claims 4, 6, 11 and 13 include or have been amended to include the same or similar limitations of claim 1. Accordingly, independent claims 4, 6, 11 and 13 also overcome the rejection under 35 U.S.C. § 103(a) as being unpatentable over Turcott ‘675 in view of Montserrat et al. further in view of Krachman et al. at least for the reasons discussed above.

Furthermore, at least for the reason disclosed above, claims 2, 3, 5, 7-9 and 12, and newly added claim 15, overcome the combination of Turcott ‘675 and Montserrat further in view of Krachman because they depend on any one of independent claims 1, 4, 6 and 11. Accordingly,

Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Turcott '675 and Montserrat further in view Krachman and further in view of Thomas et al. (U.S. Pub. No. 2004/0144383, hereinafter referred to as "Thomas '383"). Applicant respectfully traverses this rejection.

Claim 5 depends from and thus incorporates the features of independent claim 1, which are neither disclosed nor suggested by Turcott '675 in view Montserrat further in view of Krachman, for the reasons stated above.

Thomas '383 does not remedy the deficiencies of Turcott '675, Montserrat or Krachman, as the various features recited above are also absent from Thomas '383. For example, Applicant's 383 claimed features of "[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure," or "a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient," are neither disclosed nor suggested by Thomas '383.

Thomas '383 discloses a gas system for supplying pressurized air for stabilizing breathing of target patients or users and a control processor. The control processor of Thomas '383 may be responsive to patient state information including ECG and EKG signals. Applicant respectfully submits that is has nothing to do with the features claimed by the Applicant, which provides an apparatus for examining patients having chronic heart failure.

The four-way combination thus similarly fails to present a prima facie case of obviousness, as the combination still fails to collectively disclose the features recited in the independent claim, let alone the additional features recited in dependant claim 5.

Accordingly, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. § 103(a) as being anticipated over being unpatentable over Turcott '675 and Montserrat further in view of Krachman and further in view of Thomas'383 be withdrawn.

Newly added claims 14 and 15.

Claim 14 recites:

“a recording medium, that is detachably attachable to the non-implantable biological information monitoring system, and that stores a biological information including the airflow information, the magnitude of respiratory airflow and the electrocardiogram wave form of the subject patient” and

an analysis unit for analyzing the enhanced state of sympathetic nerves “based on the biological information stored in the recording medium.”

Claim 15 includes the same or similar limitations. These elements are disclosed in paragraphs [0072], [0073] and [0077] of Application Publication No. US-2006/0247546-A. None of the applied art alone or in combination discloses, teaches or suggests the recording medium and the analysis unit above.

Conclusion

In view of the above amendment and remarks, applicant believes the pending application is in condition for allowance.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein,

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in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-0013, under Order No. TEI-0135 from which the undersigned is authorized to draw.

Dated: July 27, 2009

Respectfully submitted,

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